



## United States Patent and Trademark Office

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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/063,670 05/07/2002		05/07/2002	Audrey Goddard	P3230R1C001-168	7260	
30313	7590	10/20/2005		EXAM	EXAMINER	
•		NS, OLSON & BE	NICKOL,	NICKOL, GARY B		
2040 MAIN STREET IRVINE, CA 92614				ART UNIT	PAPER NUMBER	
, <b>,</b> .				1642		

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE @ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensives for time may be evaluate under the provision of 37 CPT 13/61, here event, because, may a reply be timely filled.  If NO period for reply is equicified above, the maximum statutory paried will apply and will expire SLX (6) MONTHS from the mailing date of this communication. Failurs to reply which the set or excented period for reply is equicified above, the maximum statutory paried will apply and will expire SLX (6) MONTHS from the mailing date of this communication. Failurs to reply which the set or excented period for reply will. Dy statios, cause the application Deduced. Between Path Post Ded U.S. 2, § 133, Nov yrely received by the Office fact has three months after the mailing date of this communication, even if small filled, may reduce any search granted than adjustment. Set 70 CPT 1704(6).  Status  1) Responsive to communication(s) filled on 05 August 2005.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 5-13 and 17-20 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are objected to.  5) Claim(s) is/are objected to by the Examiner.  Claim(s)		Application No.	Applicant(s)					
Carry B. Nickol Ph.D.   1642    - The MAILING DATE of this communication appears on the cover sheat with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of the more by a smallest moder the provision 3 CPR 1.136(s), in the sweet, knowers, may reply but intend for the provision of the provision of STOR 1.136(s), in the sweet, knowers, may reply but intend for different provision in the provision of the communication of the commu		10/063,670	GODDARD ET AL.					
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Status     Responsive to communication(s) filed on <u>05 August 2005.</u>	<ul> <li>WHICHEVER IS LONGER, FROM THE MAILING DATE of the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period we failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing</li> </ul>	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timed will expire SIX (6) MONTHS from a cause the application to become ABANDONE	l. ely filed the mailing date of this communication. D (35 U.S.C. § 133).					
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Art Unit: 1642

Re: Goddard et al.

Date of priority: 10/29/1997

Request for Continued Examination

The request filed on 08-05-2005 for a Continued Examination (RCE) under 37

CFR 1.114 based on parent Application No. 10/063510 is acceptable and a RCE has been

established. An action on the RCE follows.

Claims 5-13, 17-20 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be

found in a prior Office Action.

Rejections Maintained:

Claims 5-13, 17-20 remain rejected under 35 U.S.C. 101 because the claimed

invention is not supported by either a specific asserted utility or a well established utility

for the reasons of record as set forth in the Actions mailed 09-13-2004 and 05-04-2005

and as further set forth below.

Applicant's arguments (Response, page 4) are accompanied by a Declaration

under 37 C.F.R. 1.132 from one of the inventors, Dr. Paul Godowski.

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Parts 1-3 of the declaration merely describe the experimental procedures used to measure TNF-α release from human blood in-vitro and therefore do not constitute any substantial arguments that particularly address the utility of the claimed invention.

Part 4 of the declaration argues that the assay was conducted using well-accepted and established scientific procedures and that the results reported in Example 17 are reliable and reproducible. This argument has been considered but is not found relevant. While the results may be reproducible and or reliable, such arguments do not address a substantial or specific utility regarding TNF-α release from the blood. Dr. Godowski argues that PRO polypeptides reported as positive in the assay stimulated the release of at least 50-fold and up to more than 300-fold more TNF-α than the control samples. In contrast, Dr. Godowski notes that TNF-α is normally undetectable in human blood. Again, however, such statements regarding release of TNF-α fail to ascribe a real world utility or substantial use for increasing TNF-α in blood. Thus, the statements in Part 4 are not found persuasive.

In Part 5 of the declaration, Applicants appear to be rebutting the Examiner's discussion of the Goeddel reference (Action mailed 05-04-2005, page 4), which was first submitted by Dr. Godowski in his Declaration filed 12-14-2004 (see page 2, 1<sup>st</sup> paragraph). Presently, Dr. Godowski argues that one cannot extend the transient induction of TNF-α production by murine macrophage cells upon contact with PMA to infer that the *claimed* polypeptides will necessarily induce transient production of TNF-α in human cells. While the latter may be true, applicant's arguments do not address why any general increase in TNF-α in human blood would be of substantial utility, especially in view of the fact that that Goeddel *et al.* teaches (page 602) that increases in TNF-α can

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both inhibit the growth of cells and or stimulate the growth of cells. Applicants merely maintain (Response, page 5) that the utility requirement only mandates that the claimed polypeptide have beneficial activity with respect to at least one cell type. This argument has been considered but is not found persuasive because the utility requirements are not limited to such narrow guidelines. The question of utility is always made on a case-by-case basis taking into consideration the nature of the invention, the teachings of the prior art as well as the entire disclosure.

Dr. Godowski also argues that the in vitro assays of the Goeddel reference are not comparable to in vivo therapy. This argument has been considered but is not found persuasive as applicant's experimental conclusions also relied solely on the results from in vitro experiments. Accordingly, applicant's experiments would also not necessarily extrapolate to any proposed in vivo therapy.

Part 6 of the declaration assumes that the declaration has provided substantial evidence to support a real world utility to increasing TNF- $\alpha$  levels. However, the declaration never describes any benefit to increasing TNF- $\alpha$  levels to treat any specific condition. The declaration uses the latter to introduce the idea that *reducing* TNF- $\alpha$  may treat certain conditions. Applicants argue that inhibition of polypeptides that enhance TNF- $\alpha$  production, such as the claimed nucleic acids encoding the claimed PRO polypeptides, is useful for treating such conditions as Crohn's disease and rheumatoid arthritis. This argument has been considered but is speculative at best because there is no evidence to suggest that that the claimed PRO polypeptide is involved in stimulating TNF- $\alpha$  release under such conditions.

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Applicants further argue (Response, page 6) that stimulation of TNF-α release meets the MPEP test--that a compound have "mere identification of a pharmacological activity". This argument has been considered but is not found persuasive because there is no specific or substantial nexus between the disclosed pharmacological activity and a real-world pharmacological use that provides an immediate benefit to the public. Thus, for the reasons of record and for the reasons set forth above, applicant's arguments and the declaration have not been found persuasive and the rejection is maintained.

Claims 5-13, 17-20 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to *use* the claimed invention for the reasons of record.

Claims 6, and 9-10 remain rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention for the reasons of record.

Applicants argue (Response, page 8) that Figure 6 discloses the presence of a transmembrane domain between amino acids 235-254 of SEQ ID NO:5. Applicants argue that the demarcation of these regions of the protein also demarcate the amino acids at positions 17-234 of the polypeptide of SEQ ID NO:6. This argument has been carefully considered but is not found persuasive. The disclosure, only, of a complete amino acid sequence does not provide a written description or evidence of contemplation for any specific regions within that sequence. The disclosure itself must have also contemplated

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such regions. Thus, applicant's arguments have not been found persuasive, and the

rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-

272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri.,

8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D. **Primary Examiner** 

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**GBN** 

GARY B. NICKOL, PH.D. PRIMARY EXAMINER